IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE: '318 PATENT INFRINGEMENT LITIGATION	)	Civil Action No. 05-356-KAJ (consolidated)

PLAINTIFFS' MEMORANDUM IN OPPOSITION TO MYLAN'S MOTION FOR JUDGMENT ON THE PLEADINGS OR TO BIFURCATE PROCEEDINGS

ASHBY & GEDDES
Steven J. Balick (I.D. #2114)
John G. Day (I.D. #2403)
Tiffany Geyer Lydon (I.D. #3950)
Lauren E. Maguire (I.D. #4261)
222 Delaware Avenue, 17th Floor
P.O. Box 1150
Wilmington, DE 19899
(302) 654-1888

Attorneys for Janssen Pharmaceutica N.V., Janssen, L.P., and Synaptech, Inc.

Of Counsel:

George F. Pappas
Roderick R. McKelvie
Christopher N. Sipes
Jeffrey B. Elikan
Laura H. McNeill
COVINGTON & BURLING
1201 Pennsylvania Avenue, N.W.
Washington, DC 20004
Tel: 202-662-6000
Fax: 202-662-6291

Steven P. Berman
Office of General Counsel
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933
Tel: 732-524-2805
Fax: 732-524-5866

Dated: January 9, 2006

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

CASES

STATUTES

Defendant Mylan, joined by four of the other six defendants, asks the Court to dismiss on the pleadings plaintiffs' willfulness claim or, in the alternative, to bifurcate the claim. As explained below, controlling Federal Circuit authority precludes dismissal, and the untimely request for bifurcation should be denied both because it is unjustified and because it would result in inefficiencies and delays.

STATEMENT OF NATURE AND STAGE OF PROCEEDING

In June 2005, Janssen and Synaptech filed this litigation against seven defendants: Mylan, Teva, Barr, Purepac, Alphapharm, Dr. Reddy's Laboratories, and Par. The complaints allege that these defendants, by filing ANDAs and "paragraph IV" certifications with the federal Food and Drug Administration ("FDA"), infringed plaintiffs' patent concerning a method of using galantamine hydrobromide in the treatment of Alzheimer's disease ("the '318 patent"). Section 271(e) of Title 35 of the United States Code permits the holders of patents associated with approved drugs to sue a drug manufacturer for patent infringement if that manufacturer files an ANDA application seeking FDA approval of a bioequivalent drug before the patent has expired and the application includes a paragraph IV certification asserting that the patent is invalid.

The complaints in this consolidated action allege that each defendant's filing of its ANDA "has been, and continues to be, willful" infringement. *E.g.*, Compl. ¶ 34, *Janssen Pharmaceutica N.V. v. Mylan Pharm.*, Civ. Action No. 05-371 (D. Del. June 7, 2005). The allegations of willfulness rest on defendants' filing of ANDAs seeking approval of products with conditions of use that fall within the claims of the '318 patent and on the baselessness of the assertions in the paragraph IV certifications and in this litigation that the '318 patent is invalid. The willfulness allegation is also supported by the fact that the majority of generic drug manufacturers that filed ANDAs seeking approval to market generic galantamine hydrobromide

tablets determined not to challenge the validity of the '318 patent, and instead certified that they would not market their products until the patent expires. Additional facts being developed in discovery also support the willfulness allegation. For instance, Mylan itself fifteen years ago declined to license the '318 patent, apparently because it (like the rest of the drug development industry) was skeptical that galantamine was a useful treatment for Alzheimer's disease. This is strong evidence that Mylan knew or should have known its invalidity defense on the ground of obviousness was not made in good faith.

Mylan's motion under Rule 12(c) of the Federal Rules of Civil Procedure seeks the dismissal of plaintiffs' willfulness allegation, or in the alternative, the bifurcation and stay of discovery on willful infringement. Defendants Alphapharm, Purepac, Dr. Reddy's Laboratories, and Par have joined this motion; the other defendants have not.

SUMMARY OF ARGUMENT

1. Mylan's motion to dismiss plaintiffs' willfulness claim, joined by four other defendants, is based on its erroneous interpretation of the Federal Circuit's decision in *Glaxo v. Apotex* and its failure to acknowledge the controlling Federal Circuit decision in *Yamanouchi v. Danbury*. Those cases clearly permit a willfulness finding predicated on a baseless paragraph IV certification of invalidity, along with baseless assertions of invalidity in litigation. Relying on these decisions, this Court and other courts have permitted willfulness claims similar to plaintiffs' to proceed. Moreover, *Glaxo* reviewed a dismissal made at the conclusion of a bench trial and does not support the dismissal of a willfulness claim based on a motion for judgment on the pleadings.

2. Mylan's motion in the alternative for bifurcation of the proceedings should be denied. Bifurcation in patent cases is exceptional, and bifurcation of willfulness without damages typically is not permitted. Bifurcation in this case is particularly unwarranted because

there is a significant overlap of proof between liability and willfulness, making separation of these issues into two trials inefficient and wasteful. Moreover, Mylan and the defendants that have joined this motion have not demonstrated that they face an actual "*Quantum*"-dilemma, and thus, they cannot rely on that rationale for bifurcation.

STATEMENT OF FACTS

Janssen holds an approved new drug application (NDA) for galantamine hydrobromide tablets used in the treatment of mild to moderate dementia of the Alzheimer's type. Janssen currently markets the tablets under the name "Razadyne" (formerly called "Reminyl"). The FDA's compilation of approved drugs and their associated patents – the "Orange Book" – lists the United States Patent No. 4,663,318 ("the '318 patent") in connection with Razadyne, because the patent claims an approved use of galantamine. Compl. ¶¶ 18-21, *Janssen Pharmaceutica N.V. v. Mylan Pharm.*, Civ. Action No. 05-371 (D. Del. June 7, 2005).

The '318 patent was issued by the Patent and Trademark Office on May 5, 1987 to its inventor, Dr. Bonnie M. Davis, and it expires on December 14, 2008. It is a method-of-use patent that describes the invention of treating Alzheimer's disease using galantamine. Synaptech is the current owner of this patent, and Janssen is Synaptech's exclusive licensee. Pursuant to its licensing agreement, Janssen may develop, make, keep, use, market, and sell products containing galantamine hydrobromide to treat Alzheimer's disease in the United States. *Id.* ¶¶ 26-28.

Before Janssen became the exclusive licensee of the patent, defendant Mylan considered licensing the '318 patent from Dr. Davis. In October 1989, Mylan entered a confidentiality agreement with Dr. Davis for the purposes of considering licensing her patent in order to develop a galantamine product for treatment of Alzheimer's. In April 1990, after receiving confidential information concerning the patent from Dr. Davis and after evaluating the patent, Mylan declined to enter a licensing agreement and did not at that time pursue

development of a galantamine product. Mylan's decision was in keeping with a number of pharmaceutical manufacturers and reflects (we maintain) a skepticism in the industry at the time concerning galantamine.

In April and May 2005, the seven defendants in this case sent letters to Janssen and Synaptech stating that they had submitted abbreviated new drug applications (ANDAs) to FDA under the Hatch Waxman Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. § 355 and 35 U.S.C. §§ 156, 271(e)). The applications sought approval to market galantamine hydrobromide tablets that are purportedly bioequivalent to Razadyne. These applications included paragraph IV certifications to FDA that the '318 patent was invalid. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

At the same time that defendants submitted their ANDAs to FDA, ten other drug manufacturers[1] also submitted ANDAs for approval of galantamine hydrobromide products that are purportedly bioequivalent to Razadyne. However, these ten manufacturers did not submit paragraph IV certifications. Instead, the manufacturers agreed not to market their products until after the term of the '318 patent ended, and they submitted paragraph III certifications with respect to the '318 patent which did not challenge the patent's validity. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(III).

---

[1] These ten manufacturers are Apotex Inc., Cobalt Pharmaceuticals, Inc., Eon Labs Manufacturing, Inc., IVAX Pharmaceuticals, Inc., Mutual Pharmaceuticals Co., Ranbaxy Laboratories Ltd., Roxane Laboratories, Inc., Sandoz Inc., Sun Pharmaceutical Industries, Ltd., and Watson Laboratories, Inc.

ARGUMENT

I. Plaintiffs' Allegation of Willful Infringement Should Not Be Dismissed.

In reviewing a motion for judgment on the pleadings under Rule 12(c), the Court "must accept the allegations in the complaint as true and draw all reasonable factual inferences in favor of the plaintiff." *Turbe v. Gov't of the Virgin Islands*, 938 F.2d 427, 428 (3d Cir. 1991); *see Pfizer Inc. v. Ranbaxy Labs. Ltd.*, 321 F. Supp. 2d 612, 614-15 (D. Del. 2004). "Judgment on the pleadings should be granted only if it appears beyond doubt that [plaintiffs] can prove no set of facts . . . which would entitle [them] to relief." *Pfizer*, 321 F. Supp. 2d at 615 (citation omitted). Mylan and the other defendants joining Mylan's motion bear the burden of establishing that judgment on the pleadings is appropriate. *Id.*

Willfulness does not need to be pleaded with particularity, nor is it a matter typically decided on the pleadings. *See Ferguson Beauregard/Logic Controls v. Mega Sys., LLC*, 350 F.3d 1327, 1343 (Fed. Cir. 2003); *Jurgens v. CBK, Ltd.*, 80 F.3d 1566, 1570 (Fed. Cir. 1996). Instead, it is a "factual determination to be made after consideration of the totality of the circumstances" that evolve through the litigation. *Am. Med. Sys., Inc. v. Med. Eng'g Corp.*, 6 F.3d 1523, 1530 (Fed. Cir. 1993). No "hard and fast *per se* rules" apply to the determination of willfulness. *See Rolls-Royce Ltd. v. GTE Valeron Corp.*, 800 F.2d 1101 (Fed. Cir. 1986).

To avoid a finding of willful infringement, an alleged infringer must satisfy "an affirmative duty to exercise due care to determine whether or not he is infringing." *Knorr-Bremse Systeme Fuer Nutzfahrzeuge GmbH v. Dana Corp.*, 383 F.3d 1337, 1343 (Fed. Cir. 2004). If the alleged infringer "had no reasonable basis for believing it had a right to do the acts," then the fact-finder should determine that the infringement was willful. *Am. Med. Sys.*, 6 F.3d at 1530.

A. *Glaxo* Does Not Support Dismissal of Willfulness.

Mylan's motion to dismiss, joined by Alphapharm, Purepac, Dr. Reddy's Laboratories, and Par, rests on a misinterpretation of the holding in *Glaxo Group Ltd. v. Apotex, Inc.*, 376 F.3d 1339 (Fed. Cir. 2004). *Glaxo* involved a patent for an antibiotic drug, cefuroxime. Apotex filed an ANDA seeking to market a generic version of the drug. Its ANDA filing was "atypical." *Glaxo*, 376 F.3d at 1344. Because cefuroxime was approved under a separate provision of the Federal Food, Drug, and Cosmetic Act relating to antibiotics, Apotex was not required to submit one of the four types of certifications under 21 U.S.C. § 355(j)(2)(A) usually required of manufacturers seeking to bring a generic drug to market. *Id.* Therefore, Apotex was neither required to nor made a paragraph IV certification stating that the patent was invalid or not infringed. *Id.* In short, the patent certification requirements triggering this case were simply not at issue in *Glaxo*.

The district court found that Apotex's ANDA application infringed Glaxo's patent for cefuroxime, and that that infringement was willful. The only conduct that supported the district court's willfulness finding was that Apotex filed an ANDA. The Federal Circuit agreed with Apotex that "*the mere filing of an ANDA* cannot constitute grounds for a willful infringement determination." *Id.* at 1349 (emphasis added). In so holding, the court pointedly noted that Apotex "did not file a paragraph IV certification of any kind, let alone one that made baseless accusations of invalidity," and that Apotex had not engaged in any litigation misconduct. *Id.* at 1351. *Glaxo* therefore does not preclude a determination of willfulness in this case, where plaintiffs assert both that the paragraph IV certifications of invalidity are baseless and that the claims of invalidity made in this litigation are likewise baseless.

Mylan fails even to cite the controlling decision of the Federal Circuit in *Yamanouchi Pharm. Co. v. Danbury Pharmacal, Inc.*, 231 F.3d 1339, 1347 (Fed. Cir. 2000),

which *Glaxo* discussed extensively and reaffirmed.[2] In *Yamanouchi*, the district court had found that the defendant was guilty of willful infringement because its ANDA was accompanied by a "baseless" paragraph IV certification. *Id.* In the district court's assessment, the alleged infringer's assertion of obviousness in its certification and during the litigation "contained glaring weaknesses." *Id.* The Federal Circuit upheld the district court's findings, stating that "[w]hen [the defendant] proceeded in the face of these weaknesses, its certification amounted to baseless and unjustified misconduct. In certifying invalidity, [the defendant] disregarded its duty to exercise due care." *Id.*

Glaxo reaffirmed *Yamanouchi*'s holding, and clearly permits a willfulness claim to be sustained when a paragraph IV certification of invalidity is baseless and when the defendant has likewise made unsupportable claims of invalidity during the litigation. *Glaxo*, 376 F.3d at 1350 (In *Yamanouchi*, "this Court determined that a baseless and wholly unjustified paragraph IV certification in an ANDA filing, when combined with litigation misconduct, warranted an exceptional case finding." (quotations omitted)). Plaintiffs allege both types of conduct in this case, and thus the willfulness claim is clearly permitted under *Glaxo* and *Yamanouchi*.

---

[2] Mylan's memorandum (p. 7) adds the following bracketed material to this sentence from the *Glaxo* opinion: "[W]e now hold that the mere fact that a company has filed an application or [paragraph IV] certification cannot support a finding of willful infringement for purposes of awarding attorneys fees . . . ." (quoting from 376 F.3d at 1350-51). There is no justification for Mylan's assumption that the Federal Circuit was referring to a paragraph IV certification in this sentence, and every reason to conclude that it was not. The *Glaxo* defendant had not filed a paragraph IV certification, as the Court repeatedly noted. The Court approved making an exceptional case finding based on what we have here, a baseless paragraph IV certification and litigation misconduct. *See, e.g.*, 376 F.3d at 1350.

B. This Court and Other Courts Have Rejected Mylan's *Glaxo* Argument.

Mylan incorrectly states (p. 8) that "[d]istrict courts uniformly have applied *Glaxo* to strike or dismiss willful infringement claims based solely on the filing of a drug application containing a paragraph IV certification." In fact, this Court and other courts have rejected the same argument that Mylan and the joining defendants raise here. In *Astrazeneca v. Andrx Pharm.*, LLC, No. 04-0080 (D. Del. Aug. 11, 2004), Chief Judge Robinson noted that under *Glaxo*, "the mere filing of an ANDA . . . cannot be deemed willfulness" but it "can be one factor in a willfulness determination." 8/11/04 Tr. at 2 (Ex. A). Another court ruled similarly in *Wyeth Pharm. v. Teva Pharm.*, Civ. Action No. 03-1293 (D.N.J. Aug. 5, 2004). That court concluded that "willfulness is [] a proper issue to pursue," in light of *Glaxo* and *Yamanouchi*, because "there could be activity that would support willfulness on top of the filing of the ANDA." 8/5/04 Tr. at 167 (Ex. B).

The New Jersey federal court recently affirmed this position in a written opinion. *Novartis Pharm. Corp. v. Teva Pharm., Inc.*, No. 05-CV-1887 (D.N.J. Dec. 30, 2005). In that case, Novartis sued Teva for patent infringement based on Teva's filing of an ANDA. Teva filed a motion to strike allegations related to "exceptional" case status from the pleadings, arguing that *Glaxo* precluded a willfulness finding based on the filing of an ANDA. Slip. op. at 3-4 (Ex. C). The district court rejected the motion, reasoning that "Novartis may be able to show activity in addition to the ANDA filing to support the issue of willfulness," even though its pleadings did not contain any other details relating to willfulness. *Id.* at 4.[3]

---

[3] To the extent Mylan cites contrary rulings, those decisions rest on a misinterpretation of the holding in *Glaxo* or a belief that the only misconduct involved was the mere act of filing an ANDA or certification. *Glaxo* clearly held open the possibility that a baseless paragraph IV certification and pursuit of a baseless defense to infringement in litigation – not to mention other (continued…)

C. Plaintiff's Willfulness Claim Should Proceed.

Plaintiffs' allegations that Mylan's and the other defendants' infringing conduct was willful must be accepted as true for purposes of a motion to dismiss, and plaintiffs were not required to plead willfulness with any greater particularity. *See Ferguson Beauregard/Logic Controls*, 350 F.3d at 1343. As such, Mylan and the defendants that joined Mylan's motion have not met their burden of showing that plaintiffs' willfulness claim should be dismissed.

This case involves more than just the "mere filing" of an ANDA. Here, Mylan and the other defendants filed paragraph IV certifications claiming that the '318 patent is invalid, provided notice to plaintiffs and to FDA reflecting these assertions, and have repeated those allegations in this case. Moreover, evidence uncovered in discovery further indicates that the assertions of invalidity in the paragraph IV certifications, and defendants' pursuit of that defense in this litigation, was and is objectively baseless. Notably, of the 17 companies that filed ANDA applications for approval to market galantamine hydrobromide, 10 manufacturers chose not to challenge the validity of the '318 patent and did not file paragraph IV certifications. Mylan and the other defendants, by contrast, filed paragraph IV certifications that challenge the patent's validity but did not claim non-infringement.[4]

Mylan's assertion of invalidity based on obviousness appears particularly unreasonable. Fifteen years ago, Mylan evaluated the possibility of licensing the '318 patent in

---

conduct – can amount to willfulness. *See, e.g., Astrazeneca Pharm. v. Mayne Pharma (USA) Inc.*, No. 02 Civ. 7936, 2005 WL 2864666, at *28 (S.D.N.Y. Nov. 2, 2005).

[4] Notably, Mylan and the other defendants have failed to produce discovery related to willfulness that plaintiffs requested four months ago, including documents related to defendants' evaluation of the patent and of galantamine. Their continued refusal to produce discovery to which plaintiffs are entitled may constitute litigation misconduct and may permit this court to infer that the information is damaging to the defendants' claims of patent invalidity.

order to develop a galantamine product and turned it down, we maintain because Mylan (like others) was skeptical of galantamine's utility. Having expressed skepticism of the likely invention earlier, it is "ironic" that Mylan now claims the patent is invalid because the invention supposedly was obvious. *Amstar Corp. v. Envirotech Corp.*, 730 F.2d 1476, 1478-79 (Fed. Cir. 1984).

Importantly, this case is still only in the discovery phase. On defendants' motion to dismiss willfulness, plaintiffs are entitled to all reasonable inferences – that the defendants' paragraph IV certification of invalidity was false, and that their assertions of invalidity and (initially) non-infringement in this Court were also baseless and made in bad faith. By contrast, in *Glaxo*, the Federal Circuit's dismissal of the willfulness claim took place only after there had been full discovery and a trial. It was at that point that the district court concluded that the only conduct at issue was the "mere filing" of the ANDA. There is no indication that the *Glaxo* court would have countenanced a dismissal on the pleadings prior to trial or completion of discovery. Plaintiffs have not yet had the benefit of full discovery or trial, and there is no basis for dismissing their well-pleaded allegation of willfulness.

II. The Court Should Not Bifurcate the Trial and Should Not Stay Discovery on Willfulness.

In the alternative, Mylan, Alphapharm, Purepac, Dr. Reddy's Laboratories, and Par seek bifurcation of the willfulness issue and a stay of discovery on willfulness pending completion of the trial on patent validity. In this Circuit, bifurcation is "not to be routinely ordered." *Lis v. Robert Packer Hosp.*, 579 F.2d 819, 824 (3d Cir. 1978) (footnote omitted). Bifurcation motions are granted "on a case-by-case basis only when the separation will result in judicial economy and will not unduly prejudice any party." *Smith v. Alyeska Pipeline Serv. Co.*, 538 F. Supp. 977, 982 (D. Del. 1982); *see Lis*, 579 F.2d at 824. As the moving parties, Mylan

and the other defendants joining this motion bear the burden of establishing that "judicial economy would be promoted and no party would be prejudiced by separate trials." *Princeton Biochemicals, Inc. v. Beckman Instruments, Inc.*, 180 F.R.D. 254, 256 (D.N.J. 1997) (citation omitted); *see also Corrigan v. Methodist Hosp.*, 160 F.R.D. 55, 57 (E.D. Pa. 1995). It has not made such a showing.

Bifurcation in patent cases is the exception rather than the rule. *See Real v. Bunn-O-Matic*, 195 F.R.D. 618, 620 (N.D. Ill. 2000). "In the normal course" of such litigation, "all claims and issues . . . are presented . . . in one trial." *Johns Hopkins Univ. v. Cellpro*, 160 F.R.D. 30, 32 (D. Del. 1995). In most patent cases, separating a case into two trials creates delay and inefficiency, and prejudices the party opposing bifurcation. *See id.* at 35. Bifurcating a case into separate trials – and possibly separate appeals – "implicates additional discovery; more pretrial disputes and motion practice; empaneling another jury or imposing more on the jurors who decide the earlier phase of the litigation; deposing or recalling some of the same witnesses; and potentially engendering new rounds of trial and post-trial motions and appeals." *Kos Pharm., Inc. v. Barr Labs.*, 218 F.R.D. 387, 390-91 (S.D.N.Y. 2003). For these reasons, this Court and other courts have frequently denied bifurcation requests in patent cases. *See, e.g., UCB Societe Anonyme v. Mylan Labs.*, No. 1:04-cv-683 (N.D. Ga. Sept. 27, 2005) (Ex. D); *A.L. Hansen Mfg. Co. v. Bauer Prods., Inc.*, No. 03 C 3642, 2004 WL 1125911 (N.D. Ill. May 18, 2004); *Cardiac Pacemakers, Inc. v. St. Jude Med. Inc.*, No. IP96-1718-C-H/G, 2001 WL 699856 (S.D. Ind. May 31, 2001); *Fuji Mach. Mfg. Co. v. Hover-Davis, Inc.*, 982 F. Supp. 923 (W.D.N.Y. 1997); *Johns Hopkins Univ. v. Cellpro*, 160 F.R.D. 30 (D. Del. 1995); *Remcor Prods. Co. v. Servend Int'l, Inc.*, No. 93 C 1823, 1994 WL 594723 (N.D. Ill. Oct. 28, 1994); *Calmar, Inc. v. Emson Research, Inc.*, 850 F. Supp. 861 (C.D. Cal. 1994); *Joy Technologies, Inc. v. Flakt, Inc.*, 772 F.

Supp. 842 (D. Del. 1991); *Willemijn Houdstermaatschaapij BV v. Apollo Computer Inc.*, 707 F. Supp. 1429 (D. Del. 1989); *Kimberely-Clark Corp. v. James River Corp.*, 131 F.R.D. 607, 609 (N.D. Ga. 1989).

Courts have also denied bifurcation of willfulness claims, especially where they are not coupled with damages claims. *Kos*, 218 F.R.D. at 392. "[T]rial practicalities and the weight of authority tilt the application of Rule 42(b) against separation of willfulness from liability, absent a basis for bifurcation justified by damages claims." *Id.*; *see also Calmar*, 850 F. Supp. at 866. "[M]ost of the cases in which bifurcation has been found warranted have also entailed claims of damages and a finding by the court of a factual overlap between issues regarding willfulness and those pertaining to damages, which provided a distinct ground supporting a separate trial." *Kos*, 218 F.R.D. at 392. Efficiency considerations in a case without complex damages issues – or, as in this case, any damages issues – clearly favor one trial. *See Johns Hopkins*, 160 F.R.D. at 35.

Bifurcation would be particularly inefficient in this case because of the extensive overlap between the issues of validity and willfulness. *See Real*, 195 F.R.D. at 626 ("willfulness cannot be easily partitioned into a separate issue to be decided in a vacuum"). The insubstantial nature of defendants' invalidity assertions is very strong evidence that those assertions have not been made in good faith and that defendants' infringing activity is willful. There is, of course, a very close overlap in the proof showing that the patent is valid and the ultimate willfulness conclusion that defendants' invalidity arguments lack any substantial support and were not advanced in good faith. *See Kimberely-Clark*, 131 F.R.D. at 607 (A willfulness determination – "the defendant's state of mind when it infringed the patent" – is "a finding of fact inextricably bound to the facts underlying the alleged infringement."). There is certainly no basis for

Mylan's assertion (p. 15) that the proof of validity is "entirely different" than the proof of willfulness. To bifurcate willfulness would not only delay completion of the case, but would also result in inefficient duplication of witness time and trial presentations. A finding of willfulness will be based on the totality of the proof concerning validity and the other circumstances in the case, and the claim should be tried together with the validity issues, not separately. *See THK Am., Inc. v. NSK Co. Ltd.*, 151 F.R.D 625, 630 (N.D. Ill. 1993); *accord Cardiac Pacemakers*, 2001 WL 699856, at *3.

In addition, only some of the defendants in this case have sought bifurcation of willfulness; the others apparently share plaintiffs' preference for the more efficient and less costly approach of having only one discovery period, one round of experts, one date for dispositive motions, and one trial. It would be completely unworkable to bifurcate trial and discovery on willfulness for only some of the defendants. *See UCB Societe Anonyme*, slip op. at 3 (Ex. D) (denying bifurcation of willfulness where the court was managing several consolidated cases).

Mylan's argument (p. 16) that bifurcation will avoid a "potentially massive waste of resources" is likewise off the mark. Particularly because witnesses and other evidence addressing the validity issue are also relevant to plaintiffs' proof of the insubstantiality of defendants' invalidity assertions, including willfulness issues in the trial should not have a significant practical effect on the length of the trial presentations. As for discovery, the existing schedule is designed to accommodate all of the issues in the case, including willfulness, and it will be far more efficient to have witnesses be deposed only once, rather than giving two depositions in each of the two phases of a bifurcated proceeding.

Ultimately, Mylan's main argument for bifurcation has nothing to do with issues of efficiency. Rather, it argues that bifurcation is needed to avoid the dilemma it supposedly faces of whether to assert an advice-of-counsel defense to willfulness, and be forced to waive the attorney-client privilege on relevant issues, or whether to maintain the privilege at the risk of weakening its willfulness defense. It principally relies on the decision in *Quantum v. Tandon Corp.*, 940 F.2d 642, (Fed. Cir. 1991), but its reliance is misplaced.

The *Quantum* court noted that trial courts should consider bifurcation of willfulness "whenever the particular attorney-client communications, once inspected by the court *in camera*, reveal that the defendant is indeed confronted with this dilemma." *Id.* at 644. Accordingly, generalized allegations of a "*Quantum* dilemma" do not suffice. Courts reject *Quantum*-dilemma arguments for bifurcation where the party has not submitted attorney-client communications for *in camera* review nor shown that it in fact faces a real dilemma. *See, e.g., Spectra-Physics Lasers, Inc. v. Uniphase Corp.*, 144 F.R.D. 99, 101 (N.D. Cal. 1992); *Cardiac Pacemakers*, 2001 WL 699856, at *3 n.1; *Dentsply*, 1994 WL 376276, at *2.

Mylan, Alphapharm, Purepac, Dr. Reddy's Laboratories, and Par have not even asserted advice-of-counsel defenses, much less presented the Court with any indication that they actually face the problem described in *Quantum*. At a minimum, these defendants would have had to submit to the Court the relevant privileged materials for review by the Court, and their failure to do so means that they should not be permitted to rely on *Quantum* as a rationale for bifurcation.[5]

---

[5] In the bulk of the trial court cases cited by Mylan, the parties made such submissions, and the courts found that there was a real *Quantum* problem that should be avoided, *see, e.g., Aptargroup, Inc. v. Owens-Illinois, Inc.*, No. 02 C 5058, 2003 WL 21557632 (N.D. Ill. July 3, 2003) (Ex. H to Mylan's motion); *Arthrocare Corp. v. Smith & Nephew, Inc.*, No. 01-504, slip. (continued...)

It is also the case that Mylan and the defendants that have joined Mylan's motion have waited far too long to assert a bifurcation request. This Court on two occasions has heard and resolved disputes concerning scheduling for discovery, expert reports, pretrial and trial, and the parties are now far along in their discovery and other pretrial activities, addressed all of the issues in the case, including willfulness. Plaintiffs respectfully submit that these defendants' request for bifurcation is untimely, and it should be denied for this reason as well.

CONCLUSION

For the foregoing reasons, Mylan's, Alphapharm's, Purepac's, Dr. Reddy's, and Par's Rule 12(c) motions for dismissal of willfulness or in the alternative for bifurcation and stay of discovery on willfulness should be denied.

---

op. (D. Del. Nov. 27, 2002) (Ex. D to Mylan's motion); *Sage Prods., Inc. v. Devon Indus., Inc.*, No. 93-2403, 1994 WL 791601, at *2-3 (C.D. Cal. Jan. 25, 1994) (Ex. I to Mylan's motion), or there was a claim for damages justifying bifurcation, *see, e.g., aaiPharma, Inc. v. Barr Labs., Inc.*, No. 7:01-CV-150-F1, slip op. (E.D. Mich. Sept. 4, 2001) (Ex. K to Mylan's motion); *Novopharm v. TorPharm, Inc.*, 181 F.R.D. 308 (E.D.N.C. 1998); *Princeton Biochemicals, Inc. v. Beckman Instruments, Inc.*, 180 F.R.D. 254 (D.N.J. 1997); *Thomcast, A.G. v. Cont'l Elecs. Corp.*, No. 94-G-2486-S, slip. op. (N.D. Ala. Apr. 24, 1995) (Ex. L to Mylan's motion).

ASHBY & GEDDES

/s/ Tiffany Geyer Lydon

Steven J. Balick (I.D. #2114)
John G. Day (I.D. #2403)
Tiffany Geyer Lydon (I.D. #3950)
Lauren E. Maguire (I.D. #4261)
222 Delaware Avenue, 17th Floor
P.O. Box 1150
Wilmington, DE 19899
(302) 654-1888

Attorneys for Janssen Pharmaceutica N.V., Janssen, L.P., and Synaptech, Inc.

Of Counsel:

George F. Pappas
Roderick R. McKelvie
Christopher N. Sipes
Jeffrey B. Elikan
Laura H. McNeill
COVINGTON & BURLING
1201 Pennsylvania Avenue, N.W.
Washington, DC 20004
Tel: 202-662-6000
Fax: 202-662-6291

Steven P. Berman
Office of General Counsel
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933
Tel: 732-524-2805
Fax: 732-524-5866

Dated: January 9, 2006

CERTIFICATE OF SERVICE

I hereby certify that on the 9th day of January, 2006, the attached **PLAINTIFFS' MEMORANDUM IN OPPOSITION TO MYLAN'S MOTION FOR JUDGMENT ON THE PLEADINGS OR TO BIFURCATE PROCEEDINGS** was served upon the below-named counsel of record at the address and in the manner indicated:

John W. Shaw, Esquire — HAND DELIVERY
Young Conaway Stargatt & Taylor, LLP
The Brandywine Building
1000 West Street, 17th Floor
Wilmington, DE 19801

Daniel F. Attridge, P.C. — VIA FEDERAL EXPRESS
Kirkland & Ellis LLP
655 15th Street, N.W.
Washington, DC 20005-5793

Mary B. Matterer, Esquire — HAND DELIVERY
Morris James Hitchens & Williams LLP
222 Delaware Avenue, 10th Floor
Wilmington, DE 19801

William A. Rakoczy, Esquire — VIA FEDERAL EXPRESS
Rakoczy Molino Mazzochi Siwik LLP
6 West Hubbard Street, Suite 500
Chicago, IL 60601

Richard L. Horwitz, Esquire — HAND DELIVERY
Potter Anderson & Corroon LLP
Hercules Plaza, 6th Floor
1313 N. Market Street
P.O. Box 951
Wilmington, DE 19899

Stuart D. Sender, Esquire — VIA FEDERAL EXPRESS
Budd Larner, P.C.
150 John F. Kennedy Parkway
Short Hills, NJ 07078

John C. Phillips, Jr., Esquire — HAND DELIVERY
Phillips, Goldman & Spence, P.A.
1200 North Broom Street
Wilmington, DE 19806

Lynn M. Ulrich, Esquire — VIA FEDERAL EXPRESS
Winston & Strawn LLP
35 West Wacker Drive
Chicago, IL 60601

Richard D. Kirk, Esquire — HAND DELIVERY
The Bayard Firm
222 Delaware Avenue, Suite 900
Wilmington, DE 19899

Robert J. Gunther, Jr., Esquire — VIA FEDERAL EXPRESS
Latham & Watkins LLP
885 Third Avenue, Suite 1000
New York, NY 10022-4802

Frederick L. Cottrell, III, Esquire — HAND DELIVERY
Richards, Layton & Finger
One Rodney Square
Wilmington, DE 19801

Alan H. Bernstein, Esquire — VIA FEDERAL EXPRESS
Caesar, Rivise, Bernstein, Cohen & Pokotilow, Ltd.
1635 Market Street, 12th Floor
Philadelphia, PA 19103

Philip A. Rovner, Esquire — HAND DELIVERY
Potter Anderson & Corroon LLP
Hercules Plaza
Wilmington, DE 19801

Barbara S. Wahl, Esquire — VIA FEDERAL EXPRESS
Arent Fox PLLC
1050 Connecticut Avenue, N.W.
Washington, DC 20036-5339

/s/ Tiffany Geyer Lydon

Tiffany Geyer Lydon